UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,090	02/08/2006	Moti Harel	026086.047.29US	2449

24239 7590 08/31/2010
MOORE & VAN ALLEN PLLC
P.O. BOX 13706
Research Triangle Park, NC 27709

EXAMINER	
ORWIG, KEVIN S	

ART UNIT	PAPER NUMBER
1611	

MAIL DATE	DELIVERY MODE
08/31/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/534,090	HAREL, MOTI	
	Examiner	Art Unit	
	Kevin S. Orwig	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *87-105 and 107-123* is/are pending in the application.

4a) Of the above claim(s) *101, 102, and 117-120* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *87-100, 103-105, 107-116, and 121-123* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendments and arguments filed Jun. 3, 2010 are acknowledged and have been fully considered. Claims 87-105 and 107-123 are now pending. Claims 1-86 and 106 are cancelled; claims 87, 95, and 121 are amended; claims 101, 102, and 117-120 are withdrawn. Claims 87-100, 103-105, 107-116, and 121-123 are now under consideration.

OBJECTIONS/REJECTIONS WITHDRAWN

The rejection of claim 106 is moot in light of the claim cancellation.

The rejection of claim 95 under 35 U.S.C. 112, 1st paragraph, lack of written description, is withdrawn in light of the claim amendments.

The rejection of claim 95 under 35 U.S.C. 112, 2nd paragraph is withdrawn in light of the claim amendments.

The rejection of claims 121 and 122 under 35 U.S.C. 102(b) is withdrawn in light of the claim amendments.

The rejections of claims 87-100, 103-105, 107-116, and 121-123 under 35 U.S.C. 103(a) over KÜRZINGER, TESTER, NAKATSUKA, and VILLAMAR are withdrawn in light of the claim amendments in favor of the new rejections presented below.

NEW GROUNDS OF OBJECTION/REJECTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 87-100, 103-105, 107-116, and 121-123 are rejected under 35 U.S.C. 103(a) as being unpatentable over KÜRZINGER (U.S. 6,303,175; Issued Oct. 16, 2001) in view of TESTER (WO 99/53902; Published Oct. 28, 1999), NAKATSUKA (U.S. 4,076,846; Issued Feb. 28, 1978), and VILLAMAR (WO 02/00035; published Jan. 3, 2002), all references of record.

1. Kürzinger discloses particulate feeds for aquatic animals, especially fish, shrimps, and invertebrates (abstract; col. 2, line 65; col. 3, lines 19-25; claims 12 and 13). The preferred feed contains 0.001-50%, of a gel forming compound or compounds that may be alginate in combination with other polymers such as, *inter alia*, starches,

cellulose materials, guar gum, or gum arabic (abstract; col. 2, lines 17-26). 0.1-10% of the gel forming component(s) is especially preferred (abstract; col. 1, line 67 to col. 2, line 3; claims 1-5). Examples of the gel forming component(s) present in the range of 1.5-5.5% are provided (col. 3, lines 50-58, Variant 1). These percentages are taught with respect to compositions comprising particular water contents (e.g. 50-99% or 73-94% water) (abstract; col. 2, line 3; col. 3, lines 50-58, Variant 1), and are thus wet weights. Kürzinger specifically teaches that the gel formers can be used alone or preferably in synergistic combinations, improving the acceptance and properties of the feed (col. 2, lines 32-34). Kürzinger teaches the inclusion of emulsifiers such as lecithin for the improvement of consistency and binding of the feed mixture (col. 2, lines 44-50). Kürzinger also teaches that the compositions can be treated by drying (col. 3, lines 19-23). Kürzinger's compositions are intended to be gels that are not soluble in cold water (title; abstract; col. 3, lines 4-6). Thus, the skilled artisan would know that the components thereof should also be insoluble or only partially soluble in water as well. While Kürzinger teaches that a variety of gelling agents can be used, preferably in synergistic combinations, Kürzinger does not teach starch in combination with alginate explicitly. Nonetheless, a skilled artisan would be motivated to select these components based on the prior art.

2. For example, Tester discloses orally administrable compositions comprising alginate and starch for controlled release to the intestine (title; abstract; p. 12, lines 3-6; p. 21, lines 13-17; p. 50, lines 3-7). The compositions can be in the form of granules, tablets, and powders and used in foodstuffs (p. 30, lines 4-9). Tester teaches that the

combination of alginate and starch is symbiotic (i.e. synergistic, see p. 31, lines 20-22), each polymer contributing unique characteristics to the composition (e.g. gelling ability (alginate) and active entrapment and digestibility characteristics (starch)) (p. 16, lines 14-25; p. 31, lines 5-22). In particular, Tester teaches that "sodium alginate is a relatively cheap and effective gelling agent. It is symbiotic with starch and forms a coherent matrix" (p. 48, lines 13-15). Thus, the ordinary artisan would have been motivated to specifically select the combination of starch and alginate from the teachings of Kürzinger.

3. Kürzinger does not specify a suitable weight ratio of emulsifier to the non-digestible polymer. The ordinary artisan would have looked to the literature for guidance regarding appropriate amounts of emulsifier to include in the composition.

4. Nakatsuka discloses edible particulate compositions for use in feedstuffs, agriculture, and fisheries (abstract). Nakatsuka discloses granules (i.e. particles) comprising alginate, high-amylose starch (i.e. a non-digestible polymer as set forth in the instant specification), and lecithin (i.e. an emulsifier) (col., 15, Table 4, Example 8). Nakatsuka teaches that lecithin is particularly suitable for use with starch materials because it has a desirable affinity toward starch and has an adequate hydrophilic-lipophilic balance (col. 7, lines 59-63). Furthermore, Nakatsuka teaches that up to 10% by weight or more of lecithin can be added, as embodied in examples 7-9 and 20-23 (col. 7, line 65 to col. 8, line 6). Nakatsuka also teaches that a composition containing about 10% by weight lecithin has favorable release properties (col. 7, lines 66-68). While it is noted that only 1 part by wet weight lecithin is exemplified in examples 7-9,

the teaching of up to 10% lecithin is clear, and one of ordinary skill in the art would have recognized the advantages of the release properties in the feed production process as taught by Nakatsuka.

5. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to utilize from 1% up to 10% wet weight lecithin, in the composition of Kürzinger to provide a particulate feed composition having favorable release properties per the teachings of Nakatsuka. One would have been motivated to do so since Nakatsuka teaches that lecithin is particularly suited to similar feed compositions comprising starch, and since Nakatsuka teaches that such amounts are advantageous. Further, one would have had a high expectation of success in doing so since Kürzinger teaches the use of both starch and lecithin in the feed compositions (col. 2, lines 23 and 50; claim 3).

6. Based on the teachings of Kürzinger and Tester, the ordinary artisan would have a high expectation of success in combining alginate and any of several non-digestible polymers, particularly starch, which is taught as a synergistic combination by Tester. Regarding the amounts of these components, the artisan would be guided by Kürzinger's teaching of using a combination of these polymers wherein each could be present in amounts such that the total of the two polymeric components is between about 5.5% and 10% wet weight. Thus, the inclusion of lecithin at the levels taught by Nakatsuka would result in compositions wherein the emulsifier (i.e. lecithin) is present in a ratio of between about 1:2 relative to the non-digestible polymer. It is well within the skill of the ordinary artisan to optimize the precise amounts of these components,

particularly given the relatively narrow teachings of Kürzinger and Nakatsuka. Furthermore, there is nothing of record to show the criticality of the claimed percentage ranges.

7. Kürzinger does not teach the particle sizes recited in claims 87 and 105. Kürzinger teaches the use of a variety of natural feed components, but does not explicitly teach the inclusion of the microbes recited in claims 99-100 and does not teach bioattractants.

8. It is noted that alginate-containing beadlets and particles for aquaculture use are well known in the art and many are used as controlled release compositions. For example, Villamar discloses a bioactive food complex in the form of particles or microcapsules that comprise alginate and other non-digestible polymers as well as emulsifiers such as lecithin (p. 10, 2nd and 3rd pars.; p. 14, 3rd par.; p. 16, 2nd par.). These feed particles serve to deliver different bioactive components to the digestive tract (such as the intestines) of animals such as shrimp or fish or other livestock raised commercially to control bacterial disease in such livestock (abstract, p. 7, 2nd par.). Thus, the compositions of Villamar are controlled release compositions for the bioactive agent(s) incorporated therein. Villamar teaches the inclusion of probiotic bacteria in the compositions of the invention (abstract), and teaches that Bacillus sp., Lactobacillus sp., and other bacteria are probiotics commonly added to feeds in the animal agriculture industry (p. 6, last par.). Villamar specifically teaches the use of, *inter alia*, *Bacillus subtilis*, *Bacillus licheniformis*, and *Lactococcus lactis* (p. 6, 3rd par.; claim 6).

9. One of ordinary skill in the art would recognize that the animal agriculture industry includes such feedstock animals as mollusks, rotifers, and artemia. Furthermore, Villamar teaches adjusting the size and shape of the bioactive food complex to complement the feeding mechanism and behavior of the aquatic animal target species (p. 17, 1st and 2nd pars.). In particular, Villamar teaches the production of particles in the size range of about 20-200 μm for small/larval animals and particles from about 100-1000 μm for larger/postlarval animals. Villamar also teaches the use of bioattractants (p. 11, top par.).

10. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to include known probiotic bacteria such as Bacillus spp. in the compositions of Kürzinger. One would have been motivated to do so since Villamar teaches that probiotic bacteria are advantageous for controlling bacterial disease in aquaculture. Based on Villamar's teachings, it also would have been *prima facie* obvious to adjust the particle size of the compositions (including particles of about 150 μm) and include a bioattractant as needed to feed any cultivated aquatic animal, as would be recognized by the ordinary artisan. Further, one would have had a high expectation of success in doing so since the compositions of Villamar comprise alginate, other non-digestible polymers, and lecithin as do those of Kürzinger.

11. Nakatsuka teaches proteins and other components that qualify as bioactive agents based on the examples provided in the specification. It is noted that the terms "microstructure" and "nanostructure" have not been given special meaning in the

specification. Thus, these terms have been interpreted broadly, and encompass the natural feed components disclosed by Kürzinger, such as zooplankton. Furthermore, zooplankton are microbes (i.e. microscopic organisms) (elected species), and are clearly bioactive agents as defined in claim 98. Thus, the combination of Kürzinger, Tester, Nakatsuka, and Villamar renders claims 96 and 98 obvious. Both Kürzinger and Nakatsuka disclose compositions comprising glycerol (see col. 2, lines 35-38 of Kürzinger), which is classified by the FDA as a caloric macronutrient, reading on claim 108.

12. While the feed taught by Kürzinger is intended for aquatic animals, the ordinary artisan would readily envisage the possibility of its administration to humans, particularly, in light of Nakatsuka's teaching that the components of the composition should have no harmful effect on the human body (col. 7, lines 41-46). Since many of the species raised in aquaculture are intended for human consumption, the compositions must also be acceptable for human consumption as would be recognized by the ordinary artisan. Thus, the combination of Kürzinger, Tester, Nakatsuka, and Villamar renders claim 109 obvious.

13. As noted *supra*, the feed taught by Kürzinger is for aquatic animals, especially fish, shrimp, and invertebrates (abstract). Further Kürzinger teaches the use of the disclosed feed for ornamental fish in an aquarium (i.e. domestic animals). Since Nakatsuka teaches that the components of the composition should have no harmful effect on the human body, one of ordinary skill in the art would readily have envisioned humans as a target animal for the feeds of the invention, particularly since many of the

aquaculture species for which these feeds are intended are raised for human consumption, either directly or indirectly. Therefore, the combination of Kürzinger, Tester, Nakatsuka, and Villamar renders claims 87-100, 103-105, 107-116, and 121-123 obvious.

Response to Arguments

Applicant's arguments have been fully considered but are not persuasive. Applicant argues that the instantly claimed feed composition is created by a certain process (response, pgs. 7 and 9-11).

It is noted that no limitations regarding a process of making the feed composition are present in the instant claims. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., product by process limitations referred to on p. 7 of the response) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, even if such product-by-process limitations were present (which they are not), applicant has provided absolutely no evidence that the process referred to in the response results in a structural difference in the final product.

Applicant argues that an artisan could not select the instantly claimed combination of ingredients from Kürzinger, asserting that "hundreds of different gel formers" are taught by Kürzinger, and argues that improper hindsight has been used (response, pgs. 8 and 13-14).

First, Kürzinger specifically names only 34 specific compounds in the list pointed to by applicant, not "hundreds". Second, Tester specifically motivates the selection of starch and alginate, and this motivation has consistently been ignored by applicant. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this case, the skilled artisan would have clear motivation to select the required components given only the teachings of the prior art. No impermissible hindsight has been used.

Applicant argues that the Office has merely cited prior art disclosing all the elements of the claims, but has not considered the art as a whole (response, pgs. 12-13).

This argument is incorrect because applicant is ignoring the specific motivations cited in the prior Office Actions. Furthermore, all the cited references are concerned with similar problems in the art, namely the production of particulate feeds for aquatic animals using similar components. Thus, there is ample reason for an artisan to look to each of the cited references.

Applicant also argues that the combination of references would change the principle of operation of Kürzinger and/or render Kürzinger inoperable (response, pg.

13).

Rather than materially changing the principle of operation, the cited art merely motivates the selection of components that are taught by Kürzinger. Thus, it is unclear how applicant believes that the combination of the cited references would change the principle of Kürzinger when all that that is suggested is the selection of specific components that Kürzinger teaches. Applicant is invited to explain how doing so would change the principle of operation. Applicant appears to be arguing that each and every reference must be bodily incorporated into Kürzinger, but of course that is not the test for obviousness. In response to applicant's argument that all the properties of Nakatsuka cannot be bodily incorporated into Kürzinger, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). A *prima facie* case of obviousness has been established.

Applicant argues that Nakatsuka cannot be combined with Kürzinger, and questions whether the combination results in a soluble or insoluble feed product. Applicant states that if the product is insoluble (per Kürzinger), then Nakatsuka would be rendered unsatisfactory for its intended purpose (response, p. 13).

However, it is clear that it is not Nakatsuka, but rather Kürzinger (the primary reference) that is being modified. Thus, stating that Nakatsuka is rendered unsuitable is

an incorrect analysis, and again implies applicant's improper reliance on a bodily incorporation argument. Kürzinger teaches gelled formulations (i.e. partially or completely insoluble). Applicant is reminded that Kürzinger teaches all of the structural components claimed, and Nakatsuka and Tester are merely relied upon for motivation and teachings of certain amounts of components, about which Kürzinger is silent. Second, "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Kürzinger teaches all of the structural limitations required by the claims. Both Kürzinger and Nakatsuka are concerned with similar problems in the art. Specifically, Kürzinger discloses particulate feeds for aquatic animals, especially fish, shrimps, and invertebrates and Nakatsuka discloses edible particulate compositions for use in feedstuffs, agriculture, and fisheries. By applicant's own admission both references are concerned with molded feed compositions. Thus, there is sufficient motivation for a skilled artisan to look to both of the cited references. Nakatsuka establishes amounts and motivation for the particular components in Kürzinger, and there is no "teaching away" by combining these references. In response to applicant's argument that all the properties of Nakatsuka cannot be bodily incorporated into Kürzinger, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or

all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). A *prima facie* case of obviousness has been established.

Summary/Conclusion

Claims 87-100, 103-105, 107-116, and 121-123 are rejected; claims 1-86 and 106 are cancelled.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-

5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KSO/

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611